



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,979	08/22/2005	Yoshiyuki Ishikura	47233-0050-00-US (221578)	3212
55694 7590 10/30/2008 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER MCINTOSH III, TRAVISS C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 10/30/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,979	<b>Applicant(s)</b> ISHIKURA ET AL.	
	<b>Examiner</b> TRAVISS C. MCINTOSH III	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,17,19,22 and 24-30 is/are allowed.
- 6) ☒ Claim(s) 3-14, 18, 20-21, and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/9/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1623

### **DETAILED ACTION**

The Amendments filed 7/30/08 and d 7/9/08 have been received, entered into the record, and carefully considered. The following information provided in the amendments affect the instant application by:

Claims 1-2 have been amended.

Claims 17-30 have been added

Claims 15-16 have been withdrawn.

Remarks drawn to rejections of Office Action mailed 1/9/08 include:

101 rejections: which have been overcome by applicant's amendments and have been withdrawn.

102 rejections: which have been overcome in part by applicants arguments and have been withdrawn in part.

An action on the merits of claims 1-14 and 17-30 is contained herein below.

### ***Claim Objections***

Applicant is advised that should claim 4 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Art Unit: 1623

Applicant is advised that should claim 6 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 7 be found allowable, claim 21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 9 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 3-7, 10-12, and 14 under 35 U.S.C. 102(b) as being anticipated by Nakahara et al. (US 5,409,692) is maintained for reasons of record. Claims 17-18 and 20-21 are rejected for the same reasons.

Art Unit: 1623

Claims 3-7, 10-12, 14, 17-18 and 20-21 of the instant application are drawn to various compositions or foods comprising the compounds of claims 1 or 2 as well as methods of making the same.

Nakahara et al. disclose compositions comprising oolong tea extracts and foods and beverages containing the same (see claim 1). It is noted that while Nakahara et al. does not disclose the identity of the compounds used, it is noted that they obtained their extracts in the same manner as done in the instant application, as such, one of skill in the art would expect that the extract would indeed comprise the compounds instantly claimed. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicants argue that Nakahara would be assumed to provide compositions which contain the claimed compounds at concentrations of roughly no higher than 0.0006 weight % in their extracts and 0.000006 weight% in their compositions. And the examiner notes this is convincing for the claims which comprise an actually claimed amount of agent. Claims 3-7, 10-12, 14, 17-18, and 20-21 are silent to an amount of agent contained therein, as such, are still rejected. These claims are drawn to compositions containing at least one of the flavones in a therapeutically effective amount to treat the disease. Applicants argue that based upon Ikegaya, there is no evidence that the chemical contents of the art's compositions necessarily contain therapeutically effective amounts of these compounds. However, this is not seen to be convincing. Because a particular tea leaf has varied amounts of agents does not equate to a

Art Unit: 1623

showing that a tea leaf has varied agents. That is, because the tea leaves may have different amounts of the same chemicals does not mean they have different chemical constituents all together. Applicants have not shown that the compositions of the art do not have therapeutic activity. One would expect the compounds at any level would have some level of therapeutic activity, even at the most minute amounts, as any amount of change in the patient would meet the limitations. There is not seen to be any evidence of record showing that these amounts are not effective to treat allergic diseases.

The rejection of claims 3-14 under 35 U.S.C. 102(e) as being anticipated by Uehara et al. (US 2002/0136753 A1) is maintained for reasons of record. Claims 18, 20-21, and 23 are additionally rejected herein for the same reasons.

Uehara et al. disclose antiallergic composition comprising oolong tea extracts which can be foods, cosmetics, or pharmaceuticals (see abstract, claims 1-16). It is noted that while Uehara et al. does not disclose the identity of the compounds used, it is noted that they obtained their extracts in the same manner as done in the instant application, as such, one of skill in the art would expect that the extract would indeed comprise the compounds instantly claimed. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Applicants argue that Uehara would be assumed to provide compositions which contain the claimed compounds at concentrations of roughly no higher than 0.00008 weight % in their

Art Unit: 1623

compositions. And the examiner notes this is convincing for the claims which comprise an actually claimed amount of agent. Claims 3-7, 10-12, 14, 17-18, and 20-21 are silent to an amount of agent contained therein, as such, are still rejected. These claims are drawn to compositions containing at least one of the flavones in a therapeutically effective amount to treat the disease. Applicants argue that based upon Ikegaya, there is no evidence that the chemical contents of the art's compositions necessarily contain therapeutically effective amounts of these compounds. However, this is not seen to be convincing. Because a particular tea leaf has varied amounts of agents does not equate to a showing that a tea leaf has varied agents. That is, because the tea leaves may have different amounts of the same chemicals does not mean they have different chemical constituents all together. Applicants have not shown that the compositions of the art do not have therapeutic activity. One would expect the compounds at any level would have some level of therapeutic activity, even at the most minute amounts, as any amount of change in the patient would meet the limitations. There is not seen to be any evidence of record showing that these amounts are not effective to treat allergic diseases.

### ***Conclusion***

Claims 1-2, 17, 19, and 22-30 are allowed. The prior art is not seen to teach or fairly suggest isolated compounds as claimed, nor compounds purified to a level of at least about 0.001 weight % dry solids.

Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Traviss C McIntosh III/  
Art Unit 1623  
October 24, 2008